K043084

MAY - 2 2005

SECTION 2. 510(K) SUMMARY

2.1 ADMINISTRATIVE INFORMATION

2.1.1 Name and address

Submitted by: Velocimed Inc
11400 73rd Avenue North, Suite 134
Minneapolis, MN 55369

Contact Person: John Carline
Telephone No.: 763-463-4742
Facsimile No.: 763-488-9780

2.1.2 Device Name

Trade Name	Premere™ Delivery Sheath
Common Name	Catheter Introducer, Sheath Introducer
Classification Name	Introducer, Catheter
Product Code	DYB
Classification	Class II

2.2 INDICATION FOR USE

The Premere™ Delivery Sheath is indicated for use in intravascular introduction of therapeutic devices into the left atrium of the heart through the septal wall.

2.3 DEVICE DESCRIPTION

The Premere™ Delivery Sheath consists of a non-tapered catheter introducer and an obturator. Each are curved at the distal portion to facilitate positioning and crossing the atrial septum. The Premere™ Delivery Sheath is intended to provide a pathway for intravascular introductions of therapeutic devices into the right and left atrium.

The delivery sheath is fitted with a hemostasis valve at the proximal end to allow insertion of devices while minimizing blood loss and a side port with a three-way stopcock to provided for fluid infusion, blood sampling and pressure monitoring. The delivery sheath has a stainless steel braid and a radiopaque material on outer jacket with a high-contrast radiopaque marker at the tip.

The obturator is radiopaque with a tapered tip and is compatible with a 0.038" guiding wire.

2.4 SUBSTANTIAL EQUIVALENCE

The Premere™ Delivery Sheath covered by this submission is substantially equivalent to another legally marketed Catheter Introducer:

- X-Sept Transseptal Sheath (K012489, Appriva Medical, Inc)
- Transseptal Super Arrow-Flex Percutaneous Sheath Introducer Set (K970229, Arrow International Inc) and,
- Fast-Cath Transseptal Catheter Introducer (K964518, Daig Corp.).

The Premere™ Delivery Sheath has the same general indication for use, similar principles of operation, and similar technological characteristics as the previously cleared predicate device. The differences between the Premere™ Delivery Catheter and the predicate devices do not raise new questions of safety or efficacy.

2.5 PERFORMANCE DATA

The performance test data is provided in the 510(k) submission. The performance data demonstrates that the device complies with Velocimed product specifications and the applicable product safety standards:

- ISO 10555-1:1995(E) Sterile, Single-Use Intravascular Catheters – Part 1: General Requirements.
- ISO 10555-2:1996(E) Sterile, Single-Use Intravascular Catheters – Part 2: Angiographic Catheters.
- ISO 10993-1: 1997(E) Biological Evaluation of Medical Devices.
- ISO 11135: 1994(E) Medical Devices – Validation and routine control of ethylene oxide sterilization.
- ISO 11607: 1997(E) Packaging for terminally sterilized medical devices.
- ASTM D-4169-01 Standard Practice for Performance Testing of Shipping Container and Systems.

Performance test included dimensional verification, tensile strength, and leak/burst testing. Functional performance and safety of the delivery sheath was verified in-vivo in the swine model. Test results demonstrate that the device meets or exceeds the requirements of these standards and performs substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2005

Velomiced, Inc.
c/o Mr. John Carline
Manager of Regulatory Affairs
6550 Wedgwood Road N, Suite 150
Minneapolis, MN 55311

Re: K043084
Trade Name: Premiere™ Delivery Sheath
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: II (two)
Product Code: DYB
Dated: March 30, 2005
Received: April 01, 2005

Dear Mr. Carline:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Diana R. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 14. INDICATION FOR USE

510(k) Number: K043084

Device Name: Premere™ Delivery Sheath

Indication for Use

The Premere™ Delivery Sheath is indicated for use in intravascular introduction of therapeutic devices into the left atrium of the heart through the septal wall.

Prescription Use: X
(Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use: _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R Vochmer

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K043084